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10/578,725	05/10/2006	Shingo Kawasaki	1070.46175X00	3353

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EXAMINER

FARDANESHI, MARJAN

ART UNIT	PAPER NUMBER
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4123

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,725	Applicant(s) KAWASAKI ET AL.	
	Examiner MARJAN FARDANESH	Art Unit 4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/04/2009, 11/04/2008, 07/11/2008, 05/10/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The claims contain multiple recitations of “means for” and examiner has determined that applicant has satisfied requirements to invoke 112, 6th paragraph. Accordingly, the claims will be considered in light of the disclosures as set forth therein to the particular “means” and their equivalents.

SPECIFICATION

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase “Not Applicable” should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR
DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A
COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.

(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A

“Sequence Listing” is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required “Sequence Listing” is not submitted as an electronic document on compact disc).

The headings of the application differ from the headings above. Also, the “brief explanation of the drawings” should appear between brief summary of the invention and detailed description of the invention.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-6, 9-11 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "signal separating means" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 4 and 5 recite the limitation "multiple component signals". There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "specified component signals" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "predetermined reference signal" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "differential waveforms" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "specified component signals" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "independent component waveforms" in line 4.

There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "multiple component signals" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Note : For the purpose of examination, since the WO 0232317 is not in English, U.S.

Patent No. 7,463,916 was used as translation to WO 0232317.

Claims 1-11,13-19 are rejected under 35 U.S.C. 103(a) as being obvious over Kawasaki et al. U.S. Patent No.7,463,916 in view of U.S. Patent No. 6,701,170 to Stetson.

With respect to claim 1, Kawasaki et al. discloses an optical measurement apparatus for living body comprising a means for irradiating visible to infrared light(column 6, lines 33-39) onto an object to be examined (column 3, lines 18-22), a means for detecting light transmitted inside said object and generates signals corresponding to the detected amount of light(column 3 lines 22-34), a signal processing means for processing the signals and generating biological signals of the object to be examined (fig.1 unit 19) and a display means(figures 5-9) for displaying the biological signals generated by said signal processing means (column 3 lines 41-45); While Kawasaki et al. discloses signal processing means, he does not specifically disclose signal separating means and reconstruction means.

Stetson teaches signal processing means comprising at least one signal separating means(column 4, lines 8-31) for separating the biological signals into multiple component signals (column 4, lines 8-31) and a signal reconstruction means(the examiner interprets "signal reconstruction" as inherently being done by the signal processing unit, where in the processing unit takes the source signals and deconstructs them into multiple components and then reconstruct them into specified component signals) for reconstructing the biological signals by using specified

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component signals, excluding those containing noise (column 7, lines 1- 9) of said multiple component signals. It would have been obvious to one having ordinary skills in art at the time invention was made to modify the optical measurement apparatus of Kawasaki et al. with the signal processing means of Stetson, since such modification would have provided separating unknown source signals into multiple components in order to obtain desired physiological data and the removal of undesired interference sources (e.g. noise).

With respect to claim 2, wherein said displaying means displays separated component signals and reconstructed signals, respectively (column 3 lines 41-45). The display of Kawasaki et al. is capable of displaying the reconstructed signals and separated components signals (fig.5)

With respect to claim 3, wherein the limitation of "at least two different signal separating means" (column 4, lines 8-31) does not preclude the processing means of Stetson which utilizes two steps of signal processing.

With respect to claim 4, the first step of Stetson's signal processing uses principal component analysis to separate principal components into multiple components (column 4, lines 8-31).

With respect to claim 5, Stetson further processes the independent components by using independent component analysis (column 4, lines 8-31).

With respect to claim 6, Kawasaki et al. discloses signal selecting means(column 3 lines 46-49) for selecting specified component signals to be used by said signal reconstruction means(the examiner interprets "signal reconstruction" as inherently being done by the signal processing unit, where in the processing unit takes the source signals and deconstructs them into multiple components and then reconstruct them into specified component signals) for reconstructing the biological signals by using specified component signals).

With respect to claim7, Kawasaki et al. discloses signal selecting means which selects specified component signals based on correlation values calculated at each measuring position and the pre-determined standard values (i.e. reference signal) (column8 lines 45-53)

With respect to claims 8 and 9, standard deviation is a well known mathematical technique to refine data points in further assist with selecting the specified component signals. The basic technique of refining data points with the utilization of standard deviations where the data then used in standard sorting, searching, and reporting yielded no more than the predictable outcome which one of

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ordinary skill would have expected to achieve with this common tool of the trade and was therefore an obvious expedient. The Court held that "[t]he gap between the prior art and respondent's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art." *Id.* at 230, 189 USPQ at 261.

With respect to claim 10, Kawasaki et al. discloses signal processing means through a user interface at the input/output unit (Fig.1 unit 20)

With respect to claim 11, it would have been obvious to add user data field entry selection boxes for selecting the principal component and independent component waveforms in correlation with the plot of principal component and independent component waveforms "obvious to try"-choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success.

3. With respect to claim 13, this claim is similar to claim 1 however requires multiple positions, Kawasaki et al. is modified by Stetson meets the claim limitations(column 4 lines 61-67, column 5 lines 1-10).

With respect to claims 14-19, these claims are directed to a method for removing noise from the optical signals. Kawasaki et al. discloses irradiating a light onto the examination site of an object to be examined (column 3, lines 18-22) and detecting a light transmitted through said examination site(column 3 lines 22-34), Kawasaki et al. does not specifically disclose step of analyzing components of the optical measurement

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signals and separating them into multiple component signals, and a step of reconstructing optical measurement signals by using specified component signals among the separated multiple component signals.

Stetson teaches step of analyzing components of optical measurement signals and separating them into multiple component signals (column 4, lines 8-31) and a step of reconstructing optical measurement signals by using specified component signals among the separated multiple component signals (the examiner interprets "signal reconstruction" as inherently being done by the signal processing unit, where in the processing unit takes the source signals and deconstructs them into multiple components and then reconstruct them into specified component signals) for reconstructing the biological signals by using specified component signals, It would have been obvious to one having ordinary skills in art at the time invention was made to modify the optical measurement apparatus of Kawasaki et al. with the signal processing means of Stetson, since such modification would have provided separating unknown source signals into multiple components in order to obtain desired physiological data and undesired interference sources (e.g. noise).

With respect to claim 15, the first step of Stetson's signal processing uses principal component analysis to separate principal components into multiple components (column 4, lines 8-31).

With respect to claim 16, Stetson further processes the independent components by using independent component analysis (column 4, lines 8-31).

With respect to claim 18, comprises a step for selecting specified component signals from multiple separated component signals.

With respect to claim 19, Kawasaki et al. discloses signal selecting means which selects specified component signals based on correlation values calculated at each measuring position and the pre-determined standard values (i.e. reference signal) (column8 lines 45-53) and the standard deviation is a well known mathematical technique to refine data points to further assist with selecting the specified component signals. Standard deviation is a well known mathematical technique to refine data points in further assist with selecting the specified component signals. The basic technique predictable outcome which one of ordinary skill would have expected to achieve with this common tool of the trade and was therefore an obvious expedient. the prior art and respondent's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art."/d. at 230, 189 USPQ at 261.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over

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Kawasaki et al. U.S. Patent No.7,463,916 in view of Stetson as applied to claims 1-11 above, and further in view of Keen et al. U.S. Patent No.6,264,591.

Kawasaki et al. as modified by Stetson fails to provide the user with a correlation value box for inputting the correlation value and a standard deviation box for inputting the standard deviation. Keen et al. teaches utilization of an user input box to input particular data such as correlation value, and standard deviation (keen, fig.12) in a diagnostic system. The basic technique of creating an input box for data which then enabled standard sorting, searching, and reporting would have yielded no more than the predictable outcome which one of ordinary skill would have expected to achieve with this common tool of the trade and was therefore an obvious expedient.

4. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawasaki et al. U.S. Patent No.7,463,916 in view of Stetson as applied to claims 14-17,18,19 above, and further in view of Ito et al. U.S. Patent No. 7,025,728 Kawasaki et al. as modified by Stetson fails to separate the optical measurement signals

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reconstructed by reconstruction step into multiple signals. Ito et al. teaches separating signal from the noise signal as shown in figure 11 and keeps repeating the noise separation process till the noise signal is completely separated from the source signal. Also it would have been obvious to a person with ordinary skills in the art based on Stetson's teaching to repeat the signal separation process in order to obtain desired physiological data and undesired interference sources (e.g. noise).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJAN FARDANESH whose telephone number is (571)270-5508. The examiner can normally be reached on monday-thursday 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARJAN FARDANESH/

Examiner, Art Unit 4123

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774